



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/222,123	12/29/98	RAY	R 6328-21

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EXAMINER

CROSS, L

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/222,123

Applicant(s)

Ray et al

Examiner

LaToya Cross

Group Art Unit

1743

☒ Responsive to communication(s) filed on Jul 14, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-12 and 19-21 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 and 19-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1743

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on July 14, 2000 and entered as Paper No. 6. Claims 1-12, 20 and 21 are pending in the instant application. Claims 13-18 were canceled by amendment. Claim 21 was newly added.

Status of Rejections from Previous Office Action

The rejection of claims 1-4, 5-7, 10-12 under 35 U.S.C. 102b and the rejection of claims 1, 8 and 9 under 35 U.S.C. 103 over Lee '392 are withdrawn in view of Applicants' amendments to incorporate "a means for facilitating removal of at least a portion of the collection pad from the rigid strip" into the claims.

The rejection of claim 19 under 35 U.S.C. 102 and claim 20 under 35 U.S.C. 103 over Ray et al '659 and Brown, Jr '396 are withdrawn for the same reasons as stated above.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1743

2. Claims 1 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 19 contain the phrase "relatively rigid strip". It is unclear as to what Applicants intend by "relatively rigid".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 5, 7, 8, 10, 19, 20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,609,160 to Bahl et al (hereinafter Bahl et al '160).

Bahl et al '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42) through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening (28) which allows the oral sample to be extracted during centrifugation. At col. 4, lines 8-14, Bahl et al '160 disclose that a portion of the absorbent pad is

Art Unit: 1743

treated with an indicator (dye) such that when sufficient fluid is taken up by the pad, a change in color occurs. Also provided are a package for return of the sample by mail, and an identification card (90) containing information for identifying the sample. See figures 1 and 10.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated within the meaning of 35 U.S.C. 102b in view of the teachings of Bahl et al '160.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 2, 3, 6, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160.

With respect to the above mentioned claims, Applicants claimed that the fluid being collected is urine, the analyte being tested is albumin, and BSA as a pretreatment agent.

Applicants also claim that the device has a plurality of collection pads and apertures.

With respect to Applicants' claim that the device is used for collecting urine and testing for albumin, these are Applicants' intended uses for the device. Since the claims are directed to the device, per se, and not a method of using it, the intended use is not accorded patentable weight. Furthermore, although Bahl et al '160 disclose the use of the device for oral fluids, and not urine, it would have been obvious to one of ordinary skill in the art that the device is suitable

Art Unit: 1743

for use in collecting urine samples to test for albumin (which is commonly tested for in urine), by preserving the urine samples with BSA. This is conventional and well known in the art.

With respect to the device containing a plurality of apertures and collection pads, it would have been obvious to one of ordinary skill in the art to incorporate multiple apertures and collection pads so that multiples tests or assays may be performed on a single support.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 U.S.C. 103 in view of the teachings of Bahl et al '160.

Response to Arguments

7. Applicant's arguments with respect to claims 1-12, 20, 21 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1743

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (703) 305-7360. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

LIC *SLC*

September 13, 2000

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700